70. The method of any one of claims 42-49, 52-59, and 62-69, wherein said probe nucleic acid comprises recombinant nucleic acid.

71. The method of claim 70, wherein said recombinant nucleic acid is labelled.--

REMARKS

Applicants have amended claims 42, 44-49, 52, and 54-59, cancelled claims 50-51 and 60-61, and added new claims 62-71. New claims 62-71 correspond to claims 42-49. Upon entry of this Amendment, claims 42-49, 52-59, and 62-71 will be pending in this application.

Priority (Paragraph 16)

The Examiner contends that the present claims receive support in application Serial No. 07/003,764, which was filed on January 16, 1987. It is unclear if the Examiner believes these claims are not supported by any of the earlier applications whose priority this application claims (i.e., 06/933,184, filed November 21, 1986; 06/916,080, filed October 6, 1986; and 06/835,228, filed March 3, 1986), or if the Examiner has simply not perused these earlier cases. Applicants respectfully request clarification of the Examiner's statement. Applicants contend that the present claims are fully supported by application Serial No. 06/835,228, which was filed on March 3, 1986.

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1300 I STREET, N. W.
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The Examiner was unable to study the foreign priority documents. Although Applicants have submitted certified copies of these documents in the prior applications, Applicants provided courtesy copies of English translations of these priority documents for the Examiner's use on March 6, 1996.

Applicants respectfully contend that the present claims are fully supported by the earliest foreign priority document (i.e., FR 86 04215, filed March 24, 1986).

Objection to the specification and rejection of claims 42-61 under 35 U.S.C. § 112, first paragraph, (Paragraph 20)

The Examiner objected to the specification and rejected claims 42-61 under 35 U.S.C. § 112, first paragraph, for failing to teach how to make and/or use Applicants' invention, i.e., failing to provide an enabling disclosure. Applicants respectfully traverse this objection and rejection.

The Examiner contends that the claims must recite hybridization and washing conditions. Paper 5, paragraph bridging pages 3 and 4. Applicants respectfully disagree that such recital is required to enable the claims. Applicants contend that it is well within the skill of the art to determine the proper hybridization conditions without undue experimentation.

However, to expedite allowance of the present claims, Applicants have amended claim 42, the independent claim, to recite "under non-stringent conditions," as suggested by the Examiner. Applicants new claim 62 recites "under stringent

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conditions." Therefore, Applicants respectfully request withdrawal of this ground of rejection.

The Examiner also based the enablement rejection on Applicants' alleged lack of guidance pertaining to nucleic acid sequences obtained from the HIV-2_{ROD} subclones disclosed in the specification. The Examiner contends this is required because the lentiviridae display considerable genomic heterogeneity. Paper 5, page 4, lines 22-23. Applicants respectfully traverse this ground for objection and rejection.

First, Applicants obtained similar results in experiments using HIV-2_{MIR} as they did in experiments using HIV-2_{ROD}. Genomic RNAs of both strains do not hybridize with any HIV-1 probes under stringent conditions, genomic RNAs of both strains hybridize slightly with two different HIV-1 gag probes, and genomic RNAs of both strains do not hybridize with an HIV-1 pol probe. Specification at page 20, line 24, through page 21, line 25. Also, an RNA insertion clone of HIV-2_{ROD} hybridized strongly under stringent conditions to DNA of both strains. Id. at page 32, lines 25-28.

Second, enablement is to be determined as of the filing date. United States Steel Corp. v. Phillips Petroleum Co., 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989); In re Hogan, 194 U.S.P.Q. 527, 537 (CCPA 1977). Indeed, later discovery of unknown variations does not render the claims nonenabled. U.S. Steel, 9 U.S.P.Q.2d at 1464, Hogan, 194 U.S.P.Q. at 537. Otherwise, "the opportunity for obtaining a basic patent upon early disclosure of a pioneer invention would be abolished." Hogan, 194 U.S.P.Q. at 537.

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As disclosed in the specification, Applicants were the first to identify and isolate HIV-2--the major cause of AIDS in West Africa. Specification, page 3, line 34, through page 6, line 7. Applicants were also the first to sequence HIV-2 epitopes and HIV-2 genes. See e.g., id. at page 17, line 10, through page 28, line 25. Therefore, Applicants' invention is fairly characterized as a pioneer invention.

As in U.S. Steel and Hogan, Applicants' original claim covered all known variations of the pioneering claimed subject matter. These variations were enabled by the specification when they filed it. However, other variations--HIV-2 isolates that the Examiner contends render the claims too broad--were later discovered. Therefore, the Examiner cannot reject claims 42-61 under 35 U.S.C. § 112, first paragraph, as not being enabled, based on the alleged nonenablement of the claims by later discovery of other HIV-2 strains.

Finally, the use of standard experimental models has often been recognized as supporting broader claims for purposes of 35 U.S.C. § 112, first paragraph. See, e.g., In re Jolles, 206 U.S.P.Q. 885, 890 (C.C.P.A. 1980)("the court has accepted tests on experimental animals as sufficient to establish utility"); Application of Hartop, 135 U.S.P.Q. 419, 426 (C.C.P.A. 1962)("inherent in the concept of the 'standard experimental animal' is the ability of one skilled in the art to make the appropriate correlations between the results actually observed in the experiments and the probable

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results").[1/] The specification utilizes, inter alia, HIV-2_{ROD}--a standard experimental strain and model for HIV-2 isolates. As in the case of standard experimental animals, at the time of this application, one skilled in the art would have expected the results obtained from HIV-2_{ROD} to be generalizable across most other HIV-2 strains.

Therefore, at the time of filing, the specification would have enabled one skilled in the art to make and use the claimed invention. Applicants respectfully request withdrawal of this objection and rejection.

The Examiner also contends that Applicants must specify the genomic location and precise fragment utilized in their invention. Paper 5, page 4, lines 9-18. Applicants respectfully traverse this contention.

Nonetheless, solely to expedite allowance of the pending claims, Applicants have amended claims 44-49 and 54-59 to recite the genomic location by nucleotide numbers. Therefore, Applicants respectfully request withdrawal of this rejection.

Finally, the Examiner rejected claims 43 and 53 for reciting nucleic acid probes comprising cDNAs. The Examiner contends that Applicants only disclosed the generation of one

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1/ Although these cases concern utility, not enablement, their logic applies equally to enablement. Both requirements are contained in the same paragraph of 35 U.S.C. § 112, and both utilize the same time frame (the filing date) and reference (one skilled in the art). Further, the close relationship between utility and enablement has often been recognized, by the PTO, see e.g., Utility Examination Guidelines, 60 Fed. Reg. 36263 (July 14, 1995); Legal Analysis Supporting Utility Examination Guidelines, and the courts, see, e.g., In re Brana, 34 U.S.P.Q.2d 1436, 1439 n.12 (Fed. Cir. 1995)(coverage of inoperative embodiments can support a rejection for lack of utility or nonenablement); Raytheon Co. v. Roper Corp., 220 U.S.P.Q. 592, 596 (Fed. Cir. 1983)(same), cert denied, 469 U.S. 835 (1984).

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specific cDNA clone (pSPE2) and that other cDNA nucleic acid sequences are not taught in the specification. Page 5, page 5, lines 2-13. Applicants respectfully traverse this ground for rejection.

Applicants respectfully contend that one skilled in the art would be able to generate cDNA clones from the sequences provided in Applicants' application. Indeed, Applicants even stated as much in their application. "The restriction maps and the genomic RNA sequences of HIV-2, or of the cDNAs obtained from its genomic RNAs are accessible to those versed in the art, since the strains of HIV-2 deposited with the CNCM can, after suitable multiplication, provide him with the genetic equipment required for the determination of these restriction maps and nucleotide sequences." Application, page 22, lines 1-8.

Applicants have provided detailed directions for preparing cDNAS from HIV-2 RNA. See, e.g., Specification, page 22, line 22 through page 24, line 13. In light of their detailed disclosure of the process for forming cDNA from HIV-2 RNA, and the detailed disclosure of the various HIV-2 sequences, Applicants respectfully contend that they have enabled one of ordinary skill in the art to make HIV-2 cDNAs without undue experimentation.

For all the above reasons, Applicants respectfully request withdrawal of the rejection of claims 42-61 under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification.

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Rejection of claims 42-61 under 35 U.S.C. § 112, second paragraph, (Paragraph 20)

The Examiner rejected claims 42-61 under 35 U.S.C. § 112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim Applicants' invention. Specifically, the Examiner objects to use of the term "corresponding." Paper 5, page 5, lines 23-24.

Solely to expedite allowance of the pending claims, and not in acquiescence to this rejection, Applicants have amended claims 42-61 to recite "comprising" or "complementary to." Therefore, this rejection is moot, and Applicants respectfully request its withdrawal.

The Examiner also rejected claims 44-49 and 54-59 as being vague and indefinite for failing to identify the source of the nucleic acid and the corresponding probe. Specifically, the Examiner contends that Applicants must recite the source of the probe and its corresponding genomic location and coordinates. Paper 5, page 6, lines 7-10. Applicants respectfully traverse this ground for rejection.

As Applicants have discussed with regard to the enablement rejection, supra, Applicants respectfully contend they need not recite particular strains of HIV-2. As also discussed with regard to the enablement rejection, supra, Applicants have amended claims 44-49 and 54-59 to specify the genomic location of the recited sequences. Therefore, Applicants respectfully request withdrawal of this rejection.

The Examiner rejected claim 52 for use of the phrase "recombinantly synthesizing a cloning vector." Specifically,

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1300 I STREET, N. W.
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the Examiner contends that this language is abstruse. Paper 5, page 6, lines 11-12. Applicants have amended claim 52 to recite "providing a recombinant cloning vector." Thus, this rejection is moot, and Applicants respectfully request its withdrawal.

Finally, the Examiner rejected claim 50 as being vague and indefinite for being misnumbered. Applicants have cancelled this claim. Therefore, this ground for rejection is moot.

For the above reasons, Applicants respectfully request withdrawal of the rejection of claims 42-61 under 35 U.S.C. § 112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim Applicants' invention.

Rejection of claims 42 and 52 under 35 U.S.C. § 102(a) (Paragraph 22)

The Examiner rejected claims 42 and 52 under 35 U.S.C. § 102(a) as being anticipated by Clavel et al. (1986). Applicants respectfully traverse this ground for rejection.

As evidenced by the official Filing Receipt, this application is a continuation of application Serial No. 08/392,613, filed February 22, 1995, which is a continuation of application Serial No. 08/075,020, filed June 11, 1993, which is a continuation of application Serial No. 07/792,524, filed November 18, 1991, which is a division of application Serial No. 07/462,908, filed January 10, 1990, which is a continuation of application Serial No. 07/150,645, filed November 20, 1987, which is a continuation-in-part of application Serial No. 07/003,764, filed January 16, 1987,

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
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which is a continuation-in-part of application Serial No. 06/933,184, filed on November 21, 1986. Therefore, Applicants' invention is at least entitled to the filing date of this application, November 21, 1986.

Clavel et al. was published in December 1986. Since Clavel et al. was published after Applicants' effective filing date of November 21, 1986, this reference cannot be cited as prior art against Applicants' invention. Therefore, Applicants respectfully request withdrawal of this rejection.

Rejection of claims 42-44 and 52-54 under 35 U.S.C. § 102(a) (Paragraph 23)

The Examiner rejected claims 42-44 and 52-54 under 35 U.S.C. § 102(a) as being anticipated by Clavel et al. (1986). As Applicants have indicated, supra, regarding the anticipation rejection of claims 42 and 52, Applicants respectfully contend that this reference is not available as prior art against their application due to the claim of benefit of application Serial No. 06/933,184, which was filed before Clavel et al. was published. Therefore, Applicants respectfully request withdrawal of this rejection.

Provisional obviousness-type double patenting rejection of claims 42-61

The Examiner provisionally rejected claims 42-61 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 42-46 and 48-50 of co-pending application Serial No. 08/392,613. Applicants respectfully traverse this ground for rejection.

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
1300 I STREET, N. W.
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As Applicants noted in their September 15, 1995, Preliminary Amendment, the present application is a division, not a continuation of Application Serial No. 08/392,613--the application cited by the Examiner.

The present claims are drawn to subject matter not elected for prosecution in predecessor applications. As Applicants noted in the Preliminary Amendment, the present claims are drawn to the subject matter of Group VI, hybridization methods, as identified in the December 11, 1992, Office Action in predecessor application 07/792,524. Application Serial No. 08/392,613 is a continuation of 08/075,020, which is a continuation of 07/792,524, the predecessor application where the Examiner required restriction.

The Patent and Trademark Office may not reject claims for obviousness-type double patenting if the later-presented claims were withdrawn from the previous application in response to a Restriction Requirement. 35 U.S.C. § 121. After Applicants traversed the December 11, 1992, restriction requirement in application Serial No. 07/792,524, the Examiner made the restriction requirement final. Therefore, since the present claims are not contained in application Serial No. 08/392,613, which is cited by the Examiner for this obviousness-type double patenting rejection, Applicants respectfully request withdrawal of this erroneous rejection.

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT
& DUNNER, L.L.P.
1300 I STREET, N. W.
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Provisional obviousness-type double patenting rejection of claims 42, 49-51, 52, and 59-61

The Examiner provisionally rejected claims 42, 49-51, 52, and 59-61 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 83 of copending application Serial No. 08/250,103. Applicants respectfully traverse this rejection.

Applicants note this is a provisional double patenting rejection; the reference is a copending application, not an issued patent. Therefore, Applicants respectfully request this rejection be held in abeyance until claims are allowed in either this case or the cited case.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, Applicants respectfully request such an extension, and such fee should also be charged to our Deposit Account.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

By: Michael T. Siekman

Michael T. Siekman
Reg. No. 36,276

Date: March 20, 1996

LAW OFFICES
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000